

Remarks

Claims 12 and 14-29 are pending in the subject application and currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 112, first and second paragraphs, and 35 U.S.C. § 102(b) (over Foresta *et al.* and Acosta *et al.*).

Claims 12, 14-27 and 29 remain rejected under 35 U.S.C. § 102(b) as anticipated by Foresta *et al.* (2002). In addition, claims 12, 14-17, 19-27 and 29 are rejected under 35 U.S.C. § 102(b) as anticipated by Acosta *et al.* (1991). The Office Action indicates that the limitations of the claims are still inherent in the teachings of Foresta *et al.* and Acosta *et al.* as evidenced by McInnes *et al.*, which provides evidence that oligozoospermic males have a higher incidence of "gamete numerical chromosomal alterations." Applicants respectfully assert that the Foresta *et al.* and Acosta *et al.* references do not anticipate the claimed invention.

It is well settled that in order for the Patent Office to establish a *prima facie* case of anticipation, each and every element of the claimed invention, arranged as required by the claim, must be found in a single prior art reference, either expressly or under the principles of inherency. See generally *In re Schreiber*, 128 F.3d 1473, 1477; *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677-78 (Fed. Cir. 1988); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). Additionally, the Patent Office cannot establish inherency merely by demonstrating that the asserted limitation is probable or possible. *In re Oerlich*, 666 F.2d 578, 581 (C.C.P.A. 1981). "Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency." *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). See also *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.")

In this case, the claims require the treatment of a male having gamete numerical chromosomal alterations. Neither Acosta *et al.* nor Foresta *et al.* provide any indication that such individuals were treated by the administration of FSH. The Office Action, recognized this gap in the teachings of Foresta *et al.* and Acosta *et al.* in the previous Office Action and now seeks to remedy this deficiency with the teachings of McInnes *et al.*, cited as teaching that infertile oligozoospermic males have a higher incidence of “gamete numerical chromosomal alterations” in an effort to demonstrate that the patient population of Foresta *et al.* has such chromosomal alterations. As noted above, the evidence used to fill the gap with respect to an asserted inherent characteristic “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.” In this case, the McInnes *et al.* does not establish that any of the individuals in the patient population taught in Foresta *et al.* has gamete numerical chromosomal alterations. As noted above, the Patent Office cannot establish inherency merely by demonstrating that the asserted limitation is probable or possible and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claim 28 remains rejected under 35 U.S.C. § 103(a) as obvious over Acosta *et al.* and in further view of Bouloux *et al.* (2001). The Office Action indicates that Bouloux *et al.* teach that CTP-FSH is safe and effective because it could lead to more convenient dosing regimens. Accordingly, it would have been obvious to one of ordinary skill in the art concerning knowledge of FSH variants and determining dosing regimens for variants is high, and given the evidence presented in Bouloux *et al.*, that the FSH-CTP was well tolerated, the person of ordinary skill in the art (the POSITA) could expect to substitute one FSH variant for another with a reasonable expectation of success. Applicants respectfully assert that the claimed invention is not obvious over the cited references.

As the Patent Office is aware, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention (*CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). Applicants, again, submit that the Patent Office has failed provide a *prima facie* case of obviousness for the claimed invention as all the elements of the claims are not taught by the

cited combination of references. Namely, the cited combination of references fails to teach the treatment of a male having gamete numerical chromosomal alterations with FSH.

As noted previously, and as acknowledged by the Examiner at page 9 of the first Office Action, Acosta *et al.* are silent with respect to patients having chromosomal abnormalities such as sperm diploidy, disomy, and aneuploidy. The Bouloux *et al.* reference, which teaches that FSH, and potentially FSH-CTP, is safe and effective for treatment of infertility, does not cure the defect of the Acosta *et al.* reference. In an effort to cure this deficiency in the teachings of Acosta *et al.*, the Office Action now relies on McInnes *et al.* as purportedly providing evidence that Acosta *et al.* and Foresta *et al.* were treating the same patient population. As noted above, evidence used to fill the gap with respect to an asserted inherent characteristic “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.” As also noted above, the Patent Office cannot establish inherency merely by demonstrating that the asserted limitation is probable or possible and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. In this case, the McInnes *et al.* does not establish that any of the individuals in the patient population taught in Acosta *et al.* or Foresta *et al.* has gamete numerical chromosomal alterations. Thus, it is respectfully submitted that the cited combination of references fails to render the claimed invention *prima facie* obvious and reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

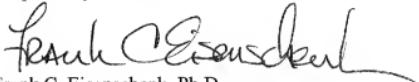
It should be understood that the remarks presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants’ agreement with or acquiescence in the Examiner’s position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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